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K001902

510(k) Summary of Safety and Effectiveness

Trade Name:	Bojrab Universal Long Implant
Common Name:	Total Ossicular Replacement Prosthesis - TORP®
Classification Name:	Total Ossicular Replacement Prosthesis (§ 874.3495)
Official Contact:	Alicia E. Farage Senior Regulatory Affairs Specialist Smith & Nephew, Inc. ENT Division 2925 Appling Road Bartlett, TN 38133
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Date Prepared:	June 21, 2000

The Bojrab Universal Long Implant is substantially equivalent to the Black Oval-Top TORP marketed by Smith & Nephew, Inc., ENT Division. It is also substantially equivalent to both the Millen Thin Head Notched Total, Non-Malleable and the Causse-Vincent Notched Narrow Partial with Short Malleable Link marketed by Medtronic Xomed Surgical Products. These devices have the same indications for use, total reconstruction of the ossicular chain that has lost its function due to disease, trauma, or congenital defect.

Intended Use

The Bojrab Universal Long Prosthesis (*Bojrab*) has the same intended use as the Black Oval-Top TORP (*Black*), Millen Thin Head Notched Total, Non-Malleable (*Millen*) and the Causse-Vincent Notched Narrow Partial with Short Malleable Link (*Causse*). All are for the reconstruction of the ossicular chain that has lost its function due to disease, trauma, or congenital defect.

Materials

The *Bojrab* uses the same materials as the *Black*. The head is made from Hydroxylapatite meeting ASTM F-1185-88. This material has a long history and wide use in middle ear reconstruction. The *Millen* and *Causse* implant heads are also manufactured from dense HA. The shaft of the *Bojrab* is made from the same material as the *Black*. It is manufactured from HAPEX, a composite material that is trimmable. This composite material is 40% hydroxylapatite and 60% high density polyethylene by volume. The *Millen* and *Causse* implant shafts are made from FLEX H/A. According to Xomed's web site, FLEX H/A is a blend of biomaterials that combines the biocompatibility for Dense H/A with handling characteristics of silicone. It is also trimmable.

Design Features

The heads of the *Bojrab*, *Millen*, and *Causse* are notched. The shafts of all of the predicate devices are trimmable. The head of the *Bojrab* is circular, as is the *Millen*. The *Black* and the *Causse* are more oval in shape. The surface area of the *Bojrab* implant head is smaller than the predicate devices. The overall length of the *Bojrab* will be 11 mm but is trimmable by the physician as needed. The length of the *Black* and *Millen* are 9 mm and the *Causse* is 14 mm long.

Differences between the Bojrab Universal Long Prosthesis and the predicate devices should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Alicia E. Farage
Senior Regulatory Affairs Specialist
Regulatory and Quality Assurance Department
Smith & Nephew
2925 Appling Road
Bartlett, TN 38133

Re: K001902
Trade Name: Bojrab Universal ~~Long Implant~~
Regulatory Class: II
Product Code: 77 ETA
Dated: June 21, 2000
Received: June 22, 2000

Dear Ms. Farage:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K001902
Device Name: Bojrab Universal Long Implant

Indications For Use:

- Otosclerosis
- Congenital fixation of the stapes
- When previous remedial surgery has been unsuccessful for the treatment of hearing loss due to otosclerosis and a significant conductive loss remains with good cochlear reserve.
- Chronic middle ear disease
- Trauma

Karen Baker

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vision of Ophthalmic Devices
(k) Number K001902